



EU Technical Documentation Assessment Certificate

This is to certify that the company

icotec ag

Industriestrasse 12
9450 Altstätten
Switzerland

SRN: CH-MF-000026833

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of
Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Technical Documentation has been verified and confirmed in Conformity
Assessment Procedures according to Article 52. The Technical Documentation is subject to
regular surveillance. Limitations to this certificate are listed in the Annex.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2
listed in the Annex may bear the CE marking with the identification number of the Notified Body
(0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex
IX, Chapter I and III is required.

Certificate registration no. 31617681 MDR2017P

Certificate ID 1000117314

Effective date 2025-03-13

Expiry date 2030-03-12

Frankfurt am Main, 2025-03-13



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745
of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.



Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: CH-MF-000026833
Certificate ID: 1000117314

Device categories and variants covered by this certificate:

Device category:	MDN 1102/A - Non-active rigid osteo- and orthopaedic implants
Product name:	KONG® VBR implants
Models:	KONG®-C VBR, KONG®-TL VBR
Risk classification:	III
Basic-UDI-DI:	76017255VBRTLBOBDA001EE, 76017255VBRTLEXTBA001TG, 76017255VBRTLSCRBA001PT, 76017255VBRTLPLABA001KW, 76017255VBRCBODBA001R4, 76017255VBRCPLABA001WL, 76017255VBRCSCRBA0012L
Intended purpose:	The KONG®-C VBR System is intended to be used for stabilization and fusion of the cervical spine following vertebral corpectomy. The KONG®-C VBR System is intended to be used with supplemental spinal fixation systems. The KONG®-TL VBR System is intended to be used for stabilization and fusion of the thoracolumbar spine following vertebral corpectomy. The KONG®-TL VBR System is intended to be used with supplemental spinal fixation systems.

Examinations and tests performed:

364530_A213328MED KONG® VBR implants dated 2024-12-16

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a